DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Hologenix, LLC
% Kit Cariquitan
Chief Regulatory Officer
Experien Group
1112 Montana Avenue, Suite 13,
Santa Monica, California 90403

June 8, 2017

Re: C160098
Product Name: Celliant performance apparel, elbow wrap, pillow, and socks
Dated: October 21, 2016
Received: October 24, 2016

Dear Kit Cariquitan:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Celliant performance tee, elbow wrap, pillow, and socks. Based on the information provided in your submission, we have determined that the Celliant performance tee, elbow wrap, pillow, and socks are medical devices as defined in section 201(h) of the Act and are also general wellness products.

The Celliant performance tee, elbow wrap, pillow, and socks are medical devices because they are intended to affect the structure or function of the body of man by temporarily promoting increased local blood flow at the site of application in healthy individuals.

Based on the information provided in your submission, we have determined that the Celliant performance tee, elbow wrap, pillow, and socks are also general wellness products. In accordance with our guidance[1], CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use as defined in the guidance, and (2) present a low risk to the safety of users and other persons. A general wellness product, for purposes of the guidance, has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

[1] See "General Wellness: Policy for Low Risk Devices" at p. 2-3. This guidance document is available for review at the following link: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf.

Our determination that the Celliant performance tee, elbow wrap, pillow, and socks are general wellness products is based on the following information provided in your submission:

(i) The intended use of the product is:
   a. Increase/More Energy
   b. Increase thermal energy
   c. This energy penetrates into the muscle and tissue to promote a temporary increase in local blood flow
   d. Better/More Endurance
   e. Faster/Quicker Recovery
   f. Enhanced/Increased Performance
   g. Increase/Enhance/More Speed
   h. Improve/Increase Strength
   i. Increase/More Stamina
   j. Recycled human energy
   k. Promotes restful sleep
   l. Helps increase comfort and promotes restful sleep
   m. Supports heat generation

(ii) The Celliant products contain infrared (IR) emitting ceramic particles

Therefore, we do not intend to enforce any applicable regulatory requirements under the Act, including premarket notification, and its implementing regulations.

Please be advised that if you claim intended uses for the Celliant performance tee, elbow wrap, pillow, and socks other than those stated above, you may need to provide supportive data in a premarket submission for such additional indications and receive marketing authorization in advance. In that event, our conclusions about the applicability of the General Wellness guidance and potential enforcement of the Act would be subject to change. FDA may need to enforce regulatory requirements under applicable provisions of the Act.

Please also note that your proposed claim "The FDA has reviewed this product and determined it to be a medical device" may incorrectly suggest that the subject devices have undergone premarket review. This information should be revised to accurately reflect the determination outlined herein. We recommend that this be revised as follows: "The FDA has determined that the Celliant performance tee, elbow wrap, pillow, and socks are medical devices as defined in section 201(h) of the Act and are general wellness products."

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of product. The response represents FDA's best judgment about how the product would be regulated, based upon the review of the information you provided, including your description of the product and its intended use. Please also note that a response to a 513(g) request is not a classification decision for a product and does not constitute FDA clearance or approval for commercial distribution.

Please be advised that this decision does not mean that the Food and Drug Administration (FDA) has made a determination that your device complies with requirements of any Federal statutes and regulations administered by other Federal agencies.

If you have any further questions regarding this letter, please contact Vivek Pinto, PhD, Chief, Physical Medicine and Rehabilitation Devices Branch, Office of Device Evaluation, at 301-796-1136 and Vivek.Pinto@fda.hhs.gov, or for general questions, please contact the Division of Industry and Consumer Education at its toll free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely,

Angela C. Krueger -S
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Angela C. Krueger
Deputy Director Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health
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